Section 5: 510(k) Summary

DEC 2 8 2012

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Date Summary Prepared:	10/10/12
Proprietary Name:	Lansinoh Powered Breast Pump
Common Name:	Powered Breast Pump
Regulatory Class:	Class II
Product Codes:	HGX
Predicate Device(s):	K092783 - Affinity Breast Pump, Lansinoh Laboratories Saglik Gerecleri Tasarim San. Tic. Ltd. Sti.

Device Description: The Powered Breast Pump provides the option of pumping on one breast or on both breasts at the same time. The Powered Breast Pump can be powered by 6 AA batteries or an AC adaptor provided with the pump. The pumping system consists of a diaphragm-type vacuum pump which is driven by a microprocessor. The user interface consists of a front panel keypad and LCD display. The user is able to adjust cycle-mode and suction level. The Powered Breast Pump is capable of providing vacuum levels from 75 to 220 mmHg with 3 different cycle modes. Mothers are able to choose the most comfortable / preferred vacuum level and cycle-mode.

The purpose of this Special 510(k) is for modifications to the previously cleared breast pump. The modifications are made to the cycle speeds and suction settings of the pump to create more comfortable settings for the nursing mother.

Intended Use: The Powered Breast Pump is intended to express and collect the breast milk of a nursing woman for the purpose of feeding the collected milk to a baby. The Powered Breast Pump is intended for a single user.

Performance Testing:

1) Suction Curves – suction curves are provided to illustrate that the performance of the Powered Breast Pump is substantially equivalent to the predicate device.
2) Back Flow Test - Additionally a backflow test was conducted to ensure satisfactory performance of the pump in the unlikely event that milk was to backflow into the pump unit.
3) Cleaning Validation Study – A cleaning validation study was conducted to validate the recommended cleaning instructions for the device.

Substantial Equivalence: The Powered Breast Pump is substantially equivalent to the predicate device, in intended use, technological characteristics and device design. The table below provides a comparison of the Powered Breast Pump to the predicate device.

Device Comparison Table

	New Device	Predicate Device
Manufacturer	Lansinoh Laboratories Saglik Gerecleri Tasarim San. Tic. Ltd. Sti.	Lansinoh Laboratories Saglik Gerecleri Tasarim San. Tic. Ltd. Sti.
Device Name	**Powered Breast Pump**	**Affinity Double Electric Breast Pump (DEBP)**
510(k) #	K122474	K092783
Intended Use	The Powered Breast Pump is intended to express and collect the breast milk of a nursing woman for the purpose of feeding the collected milk to a baby. The Powered Breast Pump is intended for a single user.	The DEBP is intended to express and collect the breast milk of a nursing woman for the purpose of feeding the collected milk to a baby.
Suction Levels (stimulation)	55 – 140 mmHg	50 – 150 mmHg
Cycles per Second (stimulation)	1.55 – 2.4	1.85 (fixed)
Suction Levels (expression)	80 – 220 mmHg	50 – 250 mmHg
Cycles per Second (expression)	0.61 – 1.52	0.51 – 1.0
Suction Settings	8	8
Power Supply	a) 6 AA alkaline batteries b) AC Adapter	a) 6 AA alkaline batteries b) AC Adapter
Pumping Option	Single or Double	Single or Double
Back Flow Protection	Yes	Yes
Let Down Function	Yes	Yes
Cycling/Suction Control Mechanism	Microprocessor	Microprocessor

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 28, 2012

Lansinoh Laboratories Saglik Gerecleri Tasarim San. Tic. Ltd. Sti.
% Ms. Calley Herzog
Consultant
Biologics Consulting Group, Inc.
13417 Quivas Street
WESTMINSTER CO 80234

Re: K122474
Trade/Device Name: Powered Breast Pump
Regulation Number: 21 CFR§ 884.5160
Regulation Name: Powered breast pump
Regulatory Class: II
Product Code: HGX
Dated: November 30, 2012
Received: December 3, 2012

Dear Ms. Herzog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner

Acting Director for:
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number: ___K122474_____

Device Name: Powered Breast Pump

Indications for Use:

The Powered Breast Pump is intended to express and collect the breast milk of a nursing woman for the purpose of feeding the collected milk to a baby. The Powered Breast Pump is intended for a single user.

Prescription Use _____ AND/OR Over-The-Counter Use ____X__

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122474